



House of Representatives

General Assembly

File No. 177

February Session, 2002

Substitute House Bill No. 5288

House of Representatives, March 26, 2002

The Committee on Public Health reported through REP. EBERLE of the 15th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING THE ESTABLISHMENT OF A BIOLOGICAL AGENTS REGISTRY.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2002*) (a) As used in this
2 section, "biological agent" means:

3 (1) Any select agent that is a microorganism, virus, bacterium,
4 fungus, rickettsia, or toxin listed in the Code of Federal Regulations,
5 Title 42, Part 72, Appendix A;

6 (2) Any genetically modified microorganisms or genetic elements
7 from an organism specified in the Code of Federal Regulations, Title
8 42, Part 72, Appendix A, shown to produce or encode for a factor
9 associated with a disease; and

10 (3) Any genetically modified microorganisms or genetic elements
11 that contain nucleic acid sequences coding for any of the toxins
12 specified in the Code of Federal Regulations, Title 42, Part 72,

13 Appendix A, or their toxic submits.

14 (b) The Commissioner of Public Health shall establish a program for
15 the registration of biological agents. The biological agents registry shall
16 identify the biological agents possessed and maintained in this state by
17 any person and shall contain such other information as required by the
18 commissioner.

19 (c) On or before December 1, 2002, any person possessing any
20 biological agent shall submit to the commissioner such information as
21 required by the commissioner, and any person who comes into
22 possession of a biological agent shall submit to the commissioner such
23 information as required by the commissioner within twenty-four hours
24 of possessing such biological agent.

25 (d) Information provided to the commissioner pursuant to this
26 section shall be confidential and shall not be a public record under
27 section 1-200 of the general statutes, as amended. The commissioner
28 may disclose such information to (1) any person for the purpose of
29 assisting the Department of Public Health in conducting or aiding in a
30 communicable disease investigation, (2) the United States Centers for
31 Disease Control and Prevention, and (3) federal and state law
32 enforcement agencies in any investigation involving the release, theft,
33 or loss of a biological agent.

34 (e) Each person possessing a biological agent shall establish
35 procedures to prevent any theft or inadvertent loss of such biological
36 agent in accordance with regulations adopted by the commissioner
37 pursuant to subsection (f) of this section.

38 (f) The commissioner shall adopt regulations, in accordance with
39 chapter 54 of the general statutes, to administer the provisions of this
40 section. Such regulations shall include: (1) The biological agents
41 required to be reported under this section; (2) the procedure for
42 persons that possess and maintain biological agents to alert the
43 commissioner and such other persons whom the commissioner
44 designates by regulation of unauthorized possession or attempted

45 possession of biological agents; and (3) the information and form for
46 submitting such information as required by the commissioner
47 pursuant to this section.

48 (g) Any person who knowingly violates the provisions of this
49 section shall be liable for a civil penalty of up to one thousand dollars
50 per violation. Each day of a continuing violation shall be a separate
51 offense.

52 (h) If the commissioner has reason to believe that a violation of this
53 section has occurred, the commissioner may send to such person or
54 officer by certified mail, return receipt requested, or personally serve
55 upon such person or officer, a notice which shall include: (1) A
56 reference to the section or sections of the general statutes or
57 regulations involved; (2) a short and plain statement of the matters
58 asserted or charged; (3) a statement of the maximum civil penalty
59 which may be imposed for such violation; and (4) a statement of the
60 party's right to request a hearing. Such request shall be submitted in
61 writing to the commissioner not later than thirty days after the notice
62 is mailed or served.

63 (i) If such person or officer so requests, the commissioner shall hold
64 a hearing on the violation asserted. The hearing shall be held in
65 accordance with the provisions of chapter 54 of the general statutes. If
66 such person or officer fails to request a hearing or fails to appear at the
67 hearing or if, after the hearing, the commissioner finds that the person
68 or officer has committed such violation, the commissioner may, in the
69 commissioner's discretion, order that a civil penalty be imposed in an
70 amount not greater than the penalty stated in the notice. The
71 commissioner shall send a copy of any order issued pursuant to this
72 subsection by certified mail, return receipt requested, to the person or
73 officer named in such order. The Attorney General, upon request of the
74 commissioner, may bring an action in superior court for the judicial
75 district of Hartford to recover such civil penalty.

This act shall take effect as follows:
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Section 1	October 1, 2002
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Statement of Legislative Commissioners:

In section 1, changes of format were made to references of "the Code of Federal Regulations, Title 42, Part 72, Appendix A", for consistency.

PH *Joint Favorable Subst.-LCO*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Fund-Type	Agency Affected	FY 03 \$	FY 04 \$
GF - Cost	Department of Public Health	161,989	127,247
GF - Cost	University of Connecticut Health Center	Minimal	Minimal
GF - Cost	Connecticut State University	Minimal	Minimal
GF - Cost	Agricultural Experiment Station	Minimal	Minimal
GF - Cost	University of Connecticut	Minimal	Minimal
GF - Cost	Office of the Attorney General	None	None

Note: GF=General Fund

Municipal Impact: None

Explanation

Implementation of this bill will result in an FY 03 state cost of \$200,891. Included in this sum is \$161,989 in expenses of the Department of Public Health (DPH) and \$38,902 in associated fringe benefits costs. The agency will need to hire one Health Program Associate (at an annual salary of \$52,228) to perform program management and one Microbiologist position to conduct investigation and enforcement activities (at an annual salary of \$39,761). Additional costs will be incurred to support database development (at \$40,000) and other expenses (at \$30,000), including supplies and postage. In FY 04 state costs will be \$167,316. This includes \$127,247 in DPH expenses and \$40,069 in fringe benefits costs.

A preliminary survey indicates that in excess of 700 organizations in Connecticut may have possession of biological agents to be registered pursuant to requirements of the bill. A potential minimal revenue gain to the state would result should civil penalties of up to \$1,000 per day be imposed upon entities found in violation of the reporting requirements. Any resulting workload increase for the Office of the

Attorney General in the course of recouping civil penalties can be accommodated within its anticipated budgetary resources.

It is anticipated that any costs incurred by the Connecticut Agricultural Experiment Station, the Connecticut University System, the University of Connecticut Health Center or the University of Connecticut in meeting requirements under both the bill and regulations to be adopted by DPH will be minimal and can be handled within existing agency resources.

OLR Bill Analysis

sHB 5288

AN ACT CONCERNING THE ESTABLISHMENT OF A BIOLOGICAL AGENTS REGISTRY**SUMMARY:**

This bill requires the public health commissioner to establish a registry for biological agents maintained in the state and requires anyone who possesses such agents to register them. It defines biological agents as specific naturally occurring or genetically modified microorganisms, virus, bacterium, fungus, rickettsia, or toxins listed in federal regulations. Registry information is confidential, but the commissioner may disclose it in some situations.

The bill requires anyone who possesses a biological agent to establish procedures to prevent its theft or inadvertent loss. Failure to register a biological agent or report unauthorized possession to the commissioner subjects the person holding the agent to a civil penalty of up to \$1,000 per day.

EFFECTIVE DATE: October 1, 2002

BIOLOGICAL AGENTS REGISTRY***Biological Agents***

The bill defines biological agent as any:

1. microorganism, virus, bacterium, fungi, rickettsia, or toxin specifically listed in the Code of Federal Regulations (42 CFR 72, Appendix A) (including ebola, eastern equine encephalitis, and smallpox viruses; anthrax and plague bacteria; and botulism, aflatoxin, and ricin);
2. genetically modified microorganism or genetic elements from any organism on the CFR list shown to produce or encode for a factor associated with a disease; and

3. genetically modified microorganism or genetic elements that contain nucleic acid sequences of any toxin on the CFR list, or their toxic submits.

Registration

The biological agents registry identifies biological agents possessed and maintained by any person in Connecticut and contains any other information the commissioner requires. Anyone possessing an agent must submit this information by December 1, 2002. Anyone who comes into possession of an agent (presumably after that date) must provide the information within 24 hours.

The information is confidential and not subject to disclosure under the Freedom of Information Act. But, the commissioner can disclose it to:

1. anyone helping the Department of Public Health in a communicable disease investigation;
2. federal and state law enforcement officials investigating the release, theft, or loss of a biological agent; and
3. the U.S. Centers for Disease Control and Prevention.

Everyone possessing a biological agent must establish procedures to prevent its loss or theft. These procedures must follow regulations the bill requires the commissioner to adopt. These regulations must also include:

1. a list of the agents that must be registered,
2. procedures for informing the commissioner and others he designates of unauthorized possession or attempted possession of an agent, and
3. the information the commissioner requires and the form for submitting it.

Violation and Penalty

Anyone who knowingly violates the bill is liable for a \$1,000 per day civil penalty as long as the violation continues.

Under the bill, if the commissioner believes a violation has occurred, he can notify the suspected violator or an officer (presumably of a corporate "person," although the bill does not otherwise appear to

make corporate officers responsible for compliance with its provisions) by personal service or certified mail, return receipt requested. The notice must reference the statutes or regulations involved; provide a short, plain statement of the charges; state the potential maximum penalty, and tell the recipient he has the right to a hearing. He must request the hearing within 30 days of receiving the notice.

The hearing must be held in accordance with the Uniform Administrative Procedures Act. If the person or officer does not ask for or fails to attend a hearing, or if the commissioner finds, after the hearing, that the person or officer committed the violation, the commissioner may impose a civil penalty of up to the amount stated in the notice. He must send the violator a copy of the penalty order by certified mail, return receipt requested. The bill authorizes the attorney general, at the commissioner's request, to bring action in Hartford Superior Court to recover the penalty.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Report

Yea 25 Nay 0